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Richard Denison
<rdenison@environmentaldefense.org>
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To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, richard.balcomb@cibasc.com

cc: MTC@mchsi.com, Karen Florini <KFlorini@environmentaldefense.org>, Richard Denison <RDenison@environmentaldefense.org>

bcc:

Subject: Environmental Defense comments on Phthalic Acid Tetrabromo Ester (CAS # 26040-51-7)

(Submitted via Internet 12/29/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and richard.balcomb@cibasc.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **Phthalic Acid Tetrabromo Ester (CAS # 26040-51-7)**.

Health and Environmental Horizons, Ltd., on behalf of the Brominated Phthalic Ester Chemistry Council and in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a test plan describing available data for phthalic acid tetrabromo ester.

Data contained in this submission address, to varying degrees, most of the SIDS elements required by the HPV Program. Additional highly desirable but not required background information on this chemical would include a discussion of its synthesis, transport and uses. This information is of particular interest because the commercial name of this chemical, Pyronil 45, as well as its molecular structure, imply that it is used as a flame retardant. As a flame retardant, this chemical may be used in numerous commercial and consumer applications that could result in human and environmental exposure. Given this, and the additional facts that the parent compound, diethylhexylphthalate, is well known to persist in the environment, and that bromination of a chemical further enhances its resistance to biodegradation, it is highly likely that phthalic acid tetrabromo ester is a very persistent environmental contaminant. Therefore, it would be of particular interest to have information regarding possible sources of its release into the environment and/or human exposure.

The test plan provides an adequate description of most chemical and physical properties of phthalic acid tetrabromo ester, but seems somewhat confused regarding the determination of photodegradation of a chemical. The relevant paragraph on page 4 implies that the sponsor believes a chemical molecule must contain a hydroxyl radical in order to photodegrade, which is not the case. Hydroxyl radicals involved in photodegradation are generated in air by sunlight.

Computer-generated data describing the environmental fate and pathways may also be of limited use. To the submitter's credit, these models have probably been run as prescribed, but, due to the very low water solubility of phthalic acid tetrabromo ester the model predictions are of questionable accuracy. For example, it is highly unlikely that the half-life of phthalic acid tetrabromo ester in soil is only two months as predicted. This speculation on our part is supported by the actual data that indicate the chemical is very resistant to biodegradation. We recommend actual studies to address these SIDS elements.

The very low water solubility of phthalic acid tetrabromo ester probably also accounts for its low mammalian toxicity upon acute administration of high acute oral or dermal doses. That is, it is probable that a high dose administered orally or dermally would not be absorbed from the gastrointestinal tract or skin. We agree that the repeat dose studies described also indicate relatively low toxicity of phthalic acid tetrabromo ester. However, no data are provided to indicate the degree to which it is absorbed from the gastrointestinal tract. Though such data are not required by the HPV program, it would be of interest to determine health risks associated with chronic low-dose exposure to this chemical, which is almost certain to bioaccumulate with repeated low-dose exposure.

The low acute toxicity of phthalic acid tetrabromo ester is cited as a justification for not conducting developmental toxicity studies. It is stated that phthalic acid tetrabromo ester has been tested at doses up to 20,000 ppm in the diet and that higher doses should not be used because doses accounting for >10% of the diet interfere with the normal nutrition of the test animals. Whereas we are not in favor of administering excessive doses or of unnecessary animal testing, a dose of 20,000 ppm actually accounts for only 2% of the diet. Thus, when we consider the importance of assuring that a persistent environmental chemical is not toxic to the developing fetus, we strongly recommend the conduct of developmental toxicity studies.

To summarize briefly, with exception of developmental toxicity, this submission has addressed most of the required SIDS elements. However, the computer models used may not have accurately predicted the environmental fate properties of phthalic acid tetrabromo ester. Given the apparent potential for phthalic acid tetrabromo ester bioaccumulation in the environment, we strongly encourage EPA to require studies of its developmental toxicity and to carefully consider the quality and suitability of all modeled data before accepting this submission for inclusion in the HPV Challenge Program.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense